IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

UNITED STATES OF AMERICA, Plaintiff, v. AZ DIABETIC SUPPLY, INC., and HISHAM ZAGHAL, Defendants.	)	No. JURY TRIAL DEMANDED

COMPLAINT OF THE UNITED STATES
(False Claims Act, Unjust Enrichment, Payment by Mistake)

The United States brings this action against AZ Diabetic Supply, Inc. (AZD) and AZD's sole owner and employee, Hisham Zaghal, for treble damages and civil penalties under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729–3733, and to recover money under the common law theory of payment by mistake and under the equitable causes of action for unjust enrichment and payment by mistake. These monies are owed to the United States because of the illegal scheme conducted by AZD and Zaghal to knowingly submit at least 923 false and fraudulent claims for payment for durable medical equipment (DME) to Medicare for reimbursement. The claims were false and fraudulent because they resulted from AZD and Zaghal purchasing complete prescriptions in knowing and willful violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a–7b(b). As a result of AZD and Zaghal's submission of 923 false and fraudulent claims in violation of the FCA and AKS, Medicare reimbursed AZD $612,329.16.

JURISDICTION AND VENUE

1. The United States brings this action pursuant to the FCA.

2. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1345 because the United States is the plaintiff. The Court also has subject matter jurisdiction over this civil action under 28 U.S.C. §§ 1331 and 1367(a) as this action arises under the FCA.

3. The Court may exercise personal jurisdiction over AZD and Zaghal pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because acts proscribed by the FCA, 31 U.S.C. § 3729, occurred in this District, and AZD and Zaghal can be found in, reside, and/or have transacted business within the Eastern District of Virginia.

4. Venue is proper in the Eastern District of Virginia under 31 U.S.C. § 3732(a), 28 U.S.C. § 1391(b), and 28 U.S.C. § 1395(a), because AZD and Zaghal are located and do business in the Eastern District of Virginia, and the acts proscribed by 31 U.S.C. § 3729, which gave rise to this action, occurred in this District.

PARTIES

5. Plaintiff is the United States, suing on its own behalf and on behalf of the Department of Health and Human Services (HHS) and its component agency, the Centers for Medicare and Medicaid Services (CMS), which administers, among other programs, the Health Insurance Program for the Aged and Disabled established by Title XVII of the Social Security Act (SSA), 42 U.S.C. §§ 1395 *et seq.* (Medicare).

6. Defendant AZD is a for-profit Virginia Corporation with its principal office address at 386 Maple Avenue, Suite 113, Vienna, Virginia 22180. AZD has been a Medicare-enrolled provider of DME since 2002.

7. Defendant Hisham "Sam" Zaghal resides in Vienna, Virginia. From 2006 through the present, Zaghal has owned and operated AZD.

STATUTORY AND REGULATORY BACKGROUND

A. The Medicare Program.

8. The Medicare Program is a federal health insurance program that provides medical benefits, items, and services to beneficiaries aged 65 and older, under 65 with certain disabilities, and of all ages with end-stage renal disease. Part B of the Medicare Program authorizes payment of federal funds for medical and other health services, including physician services, laboratory services, outpatient therapy, diagnostic services, and radiology services.

9. Under Medicare rules and regulations, Medicare Part B pays for the cost of medically-necessary orthotic braces and equipment when supplied to a beneficiary if the beneficiary has a debilitating medical condition that would be improved using an orthotic brace, and the need for the orthotic brace is documented by a licensed physician or approved medical practitioner in the form of a prescription or certification of medical necessity. Orthotic braces are commonly referred to as a type of DME under Medicare Part B.

10. Medicare providers, such as physicians or medical practices, enter into provider agreements to establish their eligibility to participate in the program. To be eligible for payment under the program, physicians or a practice must make certain certifications, including agreeing to abide by Medicare laws and regulations and acknowledging that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws such as the Anti-Kickback Statute.

11. Medicare reimburses claims for prescribed, medically-necessary DME. To be reimbursable by Medicare, the DME must be prescribed to the Medicare beneficiary by a doctor

or practitioner, often known as the "prescriber." To seek reimbursement from Medicare, a DME supplier must submit a physician's prescription and a claim for reimbursement containing, among other things, the (a) beneficiary's name, (b) beneficiary's address, (c) beneficiary's insurance I.D. number, (d) name of the prescriber, and (e) prescriber's address.

B. The False Claims Act.

12. The False Claims Act, 31 U.S.C. §§ 3729–33, as amended by Public Law 111-21, the Fraud Enforcement Recovery Act of 2009, 31 U.S.C. § 3729(a)(1)(A–C), provides in pertinent part that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (C) conspires to commit a violation of subparagraph (A), (B) . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000 . . . , plus 3 times the amount of damages which the Government sustains because of the act of that person.[1]

13. For the purposes of the False Claims Act, "knowing" and "knowingly":

> (A) mean that a person, with respect to information—
>
> (i) has actual knowledge of the information;
>
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
>
> (iii) acts in reckless disregard of the truth or falsity of the information; and

[1] For violations occurring between September 28, 1999 and November 1, 2015, the civil penalty amount ranges from a minimum of $5,500 to a maximum of $11,000. *See* 28 C.F.R. § 85.3; 64 Fed. Reg. 47099, 47103 (1999). For violations occurring on or after November 2, 2015, the civil penalty minimum and maximum have increased with inflation. *See* 28 C.F.R. § 85.5.

(B) require no proof of specific intent to defraud.

31 U.S.C. § 3729(b)(1).

14. The False Claims Act defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

C. The Anti-Kickback Statute.

15. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, makes illegal

> knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program

42 U.S.C. § 1320a-7b(b)(2).

16. The Anti-Kickback Statute further provides, "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a–7b(g).

17. Medicare's guidance manual explains that "[s]oliciting, offering, or receiving a kickback, bribe or rebate (e.g., paying for a referral of patients in exchange for the ordering of diagnostic tests and other services or medical equipment)" as an example of Medicare Fraud. Centers for Medicare & Medicaid Servs., Dep't of Health and Human Servs., *Medicare Program Integrity Manual* § 4.2.1 (2017).

FACTUAL ALLEGATIONS

18. AZD supplies DME braces and other diabetic supplies to patients.

19. AZD is a Medicare-enrolled provider. From January 2016 through December 2021, Medicare paid AZD approximately $1,297,347.08 in reimbursement claims for DME provided to persons covered by Medicare.

20. Each of the claims AZD submitted to Medicare contained one of ten Current Procedural Terminology (CPT) codes:[2]

CPT Code	Description
K0901	Knee orthosis (ko), single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf
L0648	Lumbar-sacral orthosis, sagittal control, with rigid anterior and posterior panels, posterior extends from sacrococcygeal junction to t-9 vertebra, produces intracavitary pressure to reduce load on the intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L0650	Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panel(s), posterior extends from sacrococcygeal junction to t-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include

[2] Physicians' Current Procedural Terminology is a manual published annually by the American Medical Association. It contains a listing of five-digit CPT codes that identify medical procedures performed by health care providers. At all relevant times, CMS, who administers Medicare, adopted the CPT codes for use in the Medicare program. Health care providers use CPT codes to report and bill the for services rendered to patients. When billing Medicare for a service, a health care provider identifies the service by listing the appropriate CPT code for the service on a claim form.

	padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf
L1833	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf
L1851	Knee orthosis (ko), single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf
L1971	Ankle foot orthosis, plastic or other material with ankle joint, prefabricated, includes fitting and adjustment
L3760	Elbow orthosis (eo), with adjustable position locking joint(s), prefabricated, item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L3809	Wrist hand finger orthosis, without joint(s), prefabricated, off-the-shelf, any type
L3916	Wrist hand orthosis, includes one or more nontorsion joint(s), elastic bands, turnbuckles, may include soft interface, straps, prefabricated, off-the-shelf
L3960	Shoulder elbow wrist hand orthosis, abduction positioning, airplane design, prefabricated, includes fitting and adjustment

21. At least $612,329.16 of the claims AZD submitted to Medicare during January 2016 through December 2021 arose out of prescriptions AZD purchased from marketing companies RealTime Consulting & Marketing, Inc., Quality Rx Solutions (collectively, RealTime), and LPI Media Group (LPI).

A. AZD Purchased Prescriptions And Patient Referrals From Realtime.

22. From August 2016 through April 2017, AZD purchased at least 347 prescriptions for DME from RealTime.

23. From January 2014 through July 2019, RealTime was owned and operated by Nathan LaParl. RealTime did not employ any doctors or healthcare providers.

24. RealTime purchased Medicare patients' contact information from companies that ran online marketing campaigns targeted at Medicare beneficiaries. After purchasing the Medicare patients' contact information, RealTime's call center contacted the patients, and using a script provided by RealTime, asked if they would be interested in receiving DME, such as ankle, arm, back, knee, and/or shoulder braces. The Medicare beneficiaries were told by the call center that they would receive the DME "at little to no cost." The call centers collected the Medicare beneficiary's personal and medical data, including the (a) beneficiary's name, (b) beneficiary's address, (c) beneficiary's insurance I.D. number, (d) name of beneficiary's doctor, and (e) beneficiary's doctor's address. RealTime thereafter contacted the primary care physicians of the Medicare beneficiaries to obtain DME prescriptions.

25. After RealTime obtained a DME prescription, RealTime sold the prescription directly to DME suppliers, including AZD.

26. AZD, through its owner Zaghal, paid RealTime an agreed upon fee for each prescription RealTime sold to AZD. The fee varied based on the type of brace prescribed, with RealTime earning a higher fee for more expensive braces. LaParl verified that Zaghal understood that AZD was purchasing DME prescriptions and not just patient contact information or marketing leads from RealTime.

27. RealTime sent AZD a weekly invoice via email specifying the amount AZD owed to RealTime based on the number and type of DME prescriptions RealTime sold AZD that week.

28. RealTime transferred the DME prescriptions, chart notes, accompanying patient contact information and medical records to AZD via a cloud access platform, such as DropBox or Box.

29. LaParl guaranteed to AZD that every prescription AZD purchased would be reimbursable by Medicare. Medicare, however, frequently denied coverage for the prescriptions AZD purchased from RealTime on the basis that Medicare may not reimburse for specific services when a "same or similar" service was already provided within a specified period. Accordingly, in each instance that Medicare denied coverage, Zaghal contacted LaParl and requested that LaParl provide a substitute prescription in place of the prescription for which Medicare denied coverage. LaParl complied with Zaghal's requests and provided a substitute prescription in each such instance.

30. AZD used the DME prescriptions, personal, and medical data purchased from RealTime to submit Medicare claims for reimbursement. AZD obtained reimbursement from Medicare for at least 347 prescriptions AZD purchased from RealTime, resulting in $234,978.93 in claims paid by Medicare to AZD. *See* Exhibit 1, Claims Data, Claims 1–347.

31. In approximately May 2017, RealTime stopped obtaining prescriptions and began selling AZD only patient contact and Medicare DME coverage eligibility information, also known as "qualified leads."

32. During October 2015 through May 2018, AZD paid RealTime a total of $216,775 for both prescriptions and qualified leads.

33. On January 7, 2020, LaParl pled guilty to receiving kickbacks in connection with a federal health care program, in violation of the AKS, 42 U.S.C. § 1320a–7b(b) and the HIPAA Statute, 42 U.S.C. § 1320d-6. *United States v. LaParl*, No. 20-cr-10223, Dkt. 39 (D. Mass. Jan.

1, 2021). As a part of the statement of facts accompanying his plea agreement, LaParl admitted to using RealTime to sell patient referrals developed by foreign call centers to DME companies. *Id.* at *8–9.

B. AZD Purchased Prescriptions and Patient Referrals From LPI.

34. During September 2018 through March 2019, AZD, through its owner Zaghal, purchased at least 576 prescriptions for DME from LPI.

35. From 2016 through 2020, LPI was owned and operated by Steven Churchill. LPI did not employ any doctors or healthcare providers.

36. In 2017, RealTime began selling qualified leads to LPI for $150 per lead. LPI paid telemedicine doctors to use the leads to write DME prescriptions. LPI then sold the complete prescriptions, along with each beneficiary's personal and medical data, to DME suppliers.

37. At LaParl's request, Churchill agreed to sell prescriptions to AZD.

38. AZD purchased prescriptions from LPI in exchange for a flat fee of $400 for each DME prescription.

39. LPI transferred the prescriptions, chart notes, accompanying patient contact information and medical records to AZD via DropBox.

40. AZD, through its owner Zaghal, used the DME prescriptions, personal, and medical data purchased from LPI to submit Medicare claims for reimbursement. AZD obtained reimbursement from Medicare for at least 576 prescriptions AZD purchased from LPI, resulting in $377,350.23 in claims paid by Medicare to AZD. *See* Exhibit 1, Claims Data, Claims 348–923.

41. During October 2018 through February 2019, AZD paid LPI a total of $191,800 for DME prescriptions.

42. On November 19, 2020, Churchill was indicted for receiving and soliciting kickbacks in connection with a Federal health care program, in violation of the AKS, 42 U.S.C. § 1320a–7b(b). *United States v. Steven Churchill et al.*, No. 4:20-cr-00252, Dkt. 41 (E.D. Tex. Nov. 19, 2020).

C. Zaghal Knew That Purchasing Prescriptions for Claims Submitted to Medicare Was Illegal.

43. Zaghal and AZD were aware of the requirements of the Anti-Kickback Statute. As an enrolled Medicare provider, AZD was required to certify, and did certify, through Zaghal, that the company understood that the payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with the Anti-Kickback Statute, 42 U.S.C. Section 1320a-7b(b).

44. Zaghal's knowledge of the illegality of purchasing prescriptions is evidenced by the statements Zaghal gave to law enforcement agents.

45. On October 14, 2020, HHS Office of Inspector General Special Agents interviewed Zaghal by telephone. Zaghal stated that AZD obtained prescriptions from patients' doctors and that the prescriptions were always faxed to AZD by the patients' provider. This statement was false. AZD in fact purchased more than one thousand prescriptions from RealTime and LPI. When AZD purchased prescriptions from RealTime and LPI, the prescriptions were sent to Zaghal through Dropbox or other cloud-based services by the middlemen companies, and not sent to Zaghal directly from the patients' providers.

46. When questioned about AZD's patient outreach practices prior to 2019, Zaghal stated that he purchased marketing "leads" from a telemedicine service, but Zaghal did not reveal

that he in fact purchased prescriptions. Zaghal stated that in 2018 AZD received 5 to 10 leads per week, and that AZD used these leads to contact the beneficiaries and obtain prescriptions. Zaghal did not reveal that AZD was in fact purchasing complete prescriptions, thereby negating the need for AZD to contact the beneficiaries and providers to obtain prescriptions.

47. On June 24, 2022, Zaghal was interviewed again. Zaghal stated that although he did business with LaParl/RealTime and Churchill/LPI, he did not enter a written agreement with either company. Zaghal stated that he did not recall whether he received written or verbal invoices from RealTime and LPI and asserted that he could not find copies of any invoices that he received from the companies. Zaghal declined to answer as to whether he purchased prescriptions from RealTime and LPI.

48. Zaghal falsely stated that AZD never paid RealTime and LPI a "per-lead" or "per-patient" fee. Zaghal stated that he knew a "per-patient" fee arrangement would have violated the Anti-Kickback Statute because he had a copy of the AKS posted on the wall of AZD's office. Zaghal falsely stated that he paid RealTime and LPI based on a set amount of time marketing services were performed or set fixed price.

49. Zaghal sought to hide or cover-up his wrongful conduct—the purchase of DME prescriptions—by repeatedly making false statements when questioned about AZD's purchase of prescriptions from RealTime and LPI, and his refusal to answer whether AZD purchased prescriptions from RealTime and LPI. Zaghal himself has stated that believed at the time he was in business with RealTime and LPI that it was a violation of the AKS to purchase patient referrals.

COUNT I
CAUSING THE SUBMISSION OF FALSE AND FRAUDULENT CLAIMS TO MEDICARE IN VIOLATION OF 31 U.S.C. § 3729(a)(1)(A) AND (a)(1)(B)

50. The United States repeats and realleges paragraphs 1 through 49 above.

51. During 2016 through 2019, Defendants knowingly presented and caused to be presented at least 923 materially false and fraudulent claims for reimbursement by Medicare that were materially false and fraudulent because they resulted from kickbacks Defendants knowingly and willfully paid to RealTime and LPI, in violation of 42 U.S.C. § 1320a-7b(b) & (g).

52. Defendants presented and caused these claims to be submitted to the Medicare program with actual knowledge of their falsity and fraudulence, or with reckless disregard or deliberate ignorance of whether they were false and fraudulent.

53. Medicare reimbursed AZD for a total of $612,329.16 for 923 claims resulting from kickbacks Defendants paid to RealTime and LPI.

54. A list of each such false claim submitted to the Medicare program identified by claim number and claim date is attached as Exhibit 1, Claims Data.

COUNT II
UNJUST ENRICHMENT

55. The United States repeats and realleges paragraphs 1 through 49 above.

56. During 2016 through 2019, the United States paid a total of $612,329.16 in claims for Medicare reimbursement submitted by AZD that resulted from Defendants' knowing and willful payment of kickbacks to RealTime and LPI. A list of these claims for payments is attached as Exhibit 1, Claims Data.

57. Defendants were unjustly enriched at the expense of the United States and are liable to pay $612,329.16 to the United States.

COUNT III
PAYMENT BY MISTAKE

58. Defendants' submission of at least 923 claims for Medicare reimbursement that resulted from Defendants' knowing and willful payment of kickbacks to RealTime and LPI caused AZD to receive reimbursement for claims for which AZD was not eligible to receive reimbursement. *See* Exhibit 1, Claims Data.

59. The United States paid $612,329.16 to AZD in reimbursement for Medicare claims that resulted from kickbacks based on the erroneous belief that AZD was in compliance with the Anti-Kickback Statute.

60. The United States is thus entitled to recover $612,329.16 that the Government wrongfully and erroneously paid because of Defendants' submission of Medicare claims tainted by kickbacks.

PRAYER FOR RELIEF

WHEREFORE, plaintiff United States prays for judgment against Defendants as follows:

A. That the acts alleged herein be adjudged and decreed to be unlawful in violation of the False Claims Act;

B. That the Government recover three-fold the damages of $612,329.16 caused by Defendants pursuant to 31 U.S.C. § 3729(a), and that judgment be entered against Defendants and in favor of the Government;

C. That Defendants be ordered to pay a civil penalty pursuant to 31 U.S.C. § 3729(a) for each of the at least 923 claims for payment Defendants submitted for Medicare reimbursement that resulted from kickbacks Defendants knowingly and willfully paid to RealTime and LPI.

D. To the extent not required to pay damages of $612,329.16 pursuant to 31 U.S.C. § 3729(a), that Defendants be ordered to pay restitution of $612,329.16 under the common law theories of unjust enrichment or mistake of payment.

E. Such other relief as the Court may deem just and proper, together with interest, costs, and the disbursements of this action.

JURY TRIAL DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the United States demands trial by jury as to all issues triable.

Dated: August 24, 2022

Respectfully submitted,

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